DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District Office
Nashville Branch
297 Plus Park Blvd
Nashville, TN 37217

February 19, 2003

Warning Letter No. 03-NSV-10

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mrs. Grace G. Grissom, President
Mrs. Grissom's Salads, Inc.
2500 Bransford Avenue
Nashville, Tennessee 37204

Dear Mrs. Grissom:

An inspection of your seafood salad manufacturing facility, located at 2500 Bransford Avenue, Nashville, Tennessee, conducted by investigators of the Food and Drug Administration (FDA) on December 10-12, 2002, found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Seafood HACCP [Title 21, *Code of Federal Regulations* (CFR), Part 123]. These deviations, most of which were previously brought to your attention in our letter dated February 22, 2002, cause your seafood products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Seafood HACCP information is available through links in FDA's homepage at http://www.fda.gov.

Our investigators found the following violations:

- Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with **21 CFR § 123.7(b)**. However, your corrective action plan for tuna salad at the finished product temperature critical control point to control pathogen growth is not adequate. According to current guidance, you must take sufficient measures to regain control over the operation after a critical limit deviation has occurred, and you must take appropriate action to the product involved in the critical limit deviation. You take some measures to regain control of the process but no measures to evaluate and/or dispose of the affected product.

- You must conduct a hazard analysis to determine where food safety hazards are reasonably likely to occur, and have a HACCP plan that, at a minimum, lists the critical control points, to comply with **21 CFR § 123.6(c)(2)**. However, your HACCP plan for tuna salad does not identify temperature monitoring as a control necessary for the prevention of pathogen growth during the manufacturing and distribution processes.

- You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with **21 CFR § 123.6(c)(3)**. Your HACCP plan fails to identify eggs, whey, casein, and soy as specific allergens present in your tuna salad product.

- You failed to monitor the sanitation conditions and practices to sufficiently conform to **21 CFR § 110** and subsequently **21 CFR § 123.11(b)**. The latest inspection at your facility revealed evidence of inadequate monitoring of employee hand-washing/sanitizing and toilet facilities. Also, the hot water pedal on the employee hand-washing sink in the production room was inoperable.

- You must have a written HACCP plan that lists verification steps that are adequate, to comply with **21 CFR § 123.6(c)(6)**. Your firm's HACCP plan fails to include the daily calibration of the 24-hour alarm and the routine calibration of the dial thermometer used in tuna salad production and storage. These calibrations must be performed using a NIST traceable thermometer to ensure accuracy.

- You must monitor the sanitizer strength and the frequency of its use on all production utensils and equipment to comply with **21 CFR § 110.80(b)(1)**. The employee hand sanitizer is not properly monitored to ensure the concentration is effective.

The above is not intended as an all-inclusive list of deviations. As a seafood processor, you are responsible for assuring that your plant operates in compliance with the Act, the Seafood HACCP regulations and the Current Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of the receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made and explain preventive measures to guard against future violations.

Your response should be directed to Kari L. Batey, Compliance Officer, at 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,

Carl E. Draper
District Director
New Orleans District